

## REMARKS

These remarks are in response to the final Office Action mailed July 22, 2004. Claims 1 to 4 and 6 to 9 are pending and are under consideration. Applicants respectfully request entry of the Amendment, which places the claims in better condition for allowance or for consideration on appeal.

### Regarding the Amendment

The amendment to claim 1 is supported throughout the specification. In particular, the amendment to claim 1 to delete the recitation of "said composition lacking detectable adenovirus" is supported, for example, by claim 1, as originally filed. Thus, as amendment to claim 1 is supported by the specification, and places the claims in better condition for allowance or for consideration on appeal, no new matter has been added and entry thereof is respectfully requested.

### I. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

The rejection of claims 1 to 4 and 6 to 9 under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description, is respectfully traversed. Allegedly, "the general limitation of the claimed composition to lacking detectable adenovirus defines subject matter that was not contemplated in the original disclosure." [see, Office Action, page 4]

Claims 1 to 4 and 6 to 9 are adequately described. In this regard, clearly in view of the specification, compositions lacking detectable adenovirus were contemplated. For example, the specification discloses the preparation and purification of high titers of rAAV expressing F.IX (see, for example, page 21, lines 14-16). The specification further discloses that "purified AAV-hF.IX routinely lacked detectable amounts of contaminating adenovirus, when analyzed by transduction of 293 cells followed by staining for alkaline phosphatase or  $\beta$ -galactosidase" (page 23, lines 1-4). Thus, in view of the fact that purified AAV-hF.IX was "routinely" found to lack contaminating adenovirus, a number of AAV-hF.IX compositions each free of contaminating adenovirus were prepared and, therefore, such compositions were clearly contemplated.

Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, claim 1 has been amended to delete the recitation of "said composition lacking detectable adenovirus." In view of the amendment to claim 1, the ground for rejection is moot. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

### CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 1 to 4 and 6 to 9 clearly and patentably define the invention, respectfully request that the Examiner reconsider the ground set forth in the Office Action, and respectfully request allowance of the claims now pending.

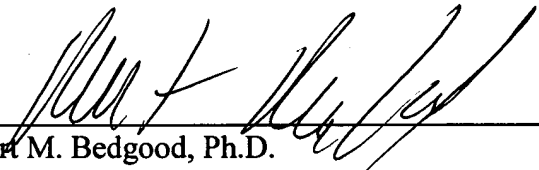
If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any additional fees, or make any credits, to Deposit Account No. 03-3975.

Respectfully submitted,

Date: \_\_\_\_\_

10.22.04

  
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